

U.S.S.N. 09/127,138
GRUENBERG
AMENDMENT

NE
instructions
do not
correspond
with spec.

- at page 41, line 26, replace "adminstration" with —administration—;
- at page 45, line 20, replace "spohdylitis" with —spondylitis—;
- at page 47, line 18, replace "synctial" with —syncytial—;
- at page 47, line 19, replace "syphillis" with —syphilis—;
- at page 47, line 28, delete the first "chaboudi";
- at page 48, line 8, replace "These" with —There—;
- at page 48, line 9, replace "rsponse" with —response—;
- at page 48, line 19, replace "muscous" with —mucous—;
- at page 48, line 23, replace "thecells" with —the cells—;
- at page 53, line 21, replace "twoeparate" with —two separate—.

IN THE CLAIMS:

Please cancel claims 18-21, 46, 47, 49, 50, 52-54, 68-71, 73-123, 125, 128-135 and 153 without prejudice or disclaimer.

Please amend claims 48, 51, 124 and 126 as follows:

48. (Amended) A method of [treating a mammal with] autologous cell therapy [regulatory immune cells], comprising:

- (a) collecting a tissue or body fluid sample comprising mononuclear cells from [the] a mammal;
- (b) activating the cells *ex vivo* to alter their cytokine production profile to produce activated T cells selected from Th1, Th1-like, Th2 and Th2-like cells;
- (c) inducing cell proliferation and cell expansion, in the absence of exogenous interleukin-2, by contacting the activated T cells with one or more mitogenic antibodies to produce a clinically relevant number of T cells selected from Th1, Th1-like, Th2 or Th2-like [regulatory immune] cells; and

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C1
C2
21 (d) reinfusing [a sufficient] at least 10^{10} [number of the] cells[to alter the
in vivo regulatory immune cell balance of the mammal].

51. The method of claim 48, wherein, prior to expansion, the cells are
treated to differentiate into Th1-like cells.

C3
124. (Amended) A method for altering the regulatory balance of immune
cells in a human, comprising administering to the human a composition comprising
[a clinically relevant number] at least 10^{10} Th1 cells [of autologous regulatory T-
cells].

C4
126. (Amended) The method of claim [16] 48, wherein at least [10^{10}] 10^{11}
cells are [administered] reinfused.

C5
127. (Amended) The method of claim [16] 48, wherein the cells that are
reinfused are Th1 cells.

REMARKS

A check for the fee for a three month extension of time accompanies this response. Any fee that may be due in connection with this application may be charged to Deposit Account No. Deposit Account No. 50-1213. If a Petition for extension of time is needed, this paper is to be considered such Petition.

Claims 48, 51, 124, 126 and 127 are pending in this application. Claims 18-21, 46, 47, 49, 50, 52-54, 68-71, 73-123, 125, 128-135 and 153 have been withdrawn from consideration as being drawn to non-elected subject matter. Applicant reserves the right to file divisional applications to the cancelled subject matter.

All pending claims find basis in the original claims in this case and, as discussed below, in the specification of the of parent application.